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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NICHOLS, CHRISTOPHER J	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 03/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,570	SCHENK, DALE B.	
	Examiner	Art Unit	
	Christopher J Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-8 and 10* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Response and Amendment filed 29 December 2003 has been received and entered *in part*. Claims 1-8 and 10 are currently pending.

Information Disclosure Statement

2. The information disclosure statement filed 29 December 2003 fails to comply with the provisions of 37 CFR §1.97, §1.98 and MPEP § 609 because References #144, #161, #162, #174, #186, #220, #222, #223, and #364 do not have a publication dates. Pursuant to 37 C.F.R. §1.98 (b)(5), References #144, #161, #162, #174, #186, #220, #222, #223, and #364 have been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR §1.97(e). See MPEP § 609 ¶C(1).

Withdrawn Objections And/Or Rejections

3. The Objection to the Specification as set forth at pp. 2 ¶2 in the previous Office Action (25 July 2003) is hereby *withdrawn* in view of Applicant's amendments (29 December 2003).

4. The Objection to the Drawings as set forth at pp. 2 ¶3 in the previous Office Action (25 July 2003) is hereby *withdrawn* in view of Applicant's replacement drawings and amendments (29 December 2003).

5. All double patenting rejections as set forth in the previous Office Action (25 July 2003) are hereby *withdrawn* in view of the complexity of the instant case family. Current double patenting rejections are included herein to take Applicant's amendments in the instant and related applications into full consideration.

6. The Rejection of claims **1-6** and **9-10** under 35 U.S.C. §102(b) as set forth at pp. 10-11 ¶25 is hereby *withdrawn* in view of Applicant's amendments (29 December 2003).

7. The Rejection of claims **1-6** and **9-10** under 35 U.S.C. §102(e) as set forth at pp. 10-11 ¶26 is hereby *withdrawn* in view of Applicant's amendments (29 December 2003).

8. All other Objections and Rejections not herein maintained or set forth are *withdrawn.*

Maintained/New Objections And/Or Rejections

Objections

9. The amendment filed 29 December 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "peptide per 2 mg of alum ~~peptide per 1 mg of alum~~" pp. 91 line 17 and "(2 mg per dose)~~(1 mg per dose)~~" pp. 92 line 3. The doubling of the dosages is not supported by the Specification as filed. Applicant is required to cancel the new matter in the reply to this Office Action.

10. The Objection to claims 3, 5, and 6 for containing non-elected subject matter as set forth at pp. 3 ¶4 in the previous Office Action (25 July 2003) is maintained. Applicant elected *without* traverse on 12 May 2003 (see MPEP 821.02).

Rejections

Provisional Obviousness-Type Non-Statutory Double Patenting

> The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
>
> A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).
>
> Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims **1-8** and **10** are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims **1-10** of copending Application No. 09/979952, claims **1-7** of Application No. 10/429216, claims **1-30** of Application No. 10/698099, and claims **56-61** and **69-70** of Application No. 10/699517 in view of Sipe (1992) "Amyloidosis" Annu. Rev. Biochem. **61**: 947-975 and US 5,780,587.

12. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of 09/979952, 10/429216, 10/698099, and 10/699517 are drawn to **pharmaceutical compositions**, comprising an agent effective to induce an immune response

against an amyloid component in a patient, including but not limited to amyloid proteins such as alpha-synuclein and Aβ, thus meeting the limitations of claims 1-10 of the instant Application 09/724570.

13. Further concerning diseases characterized by amyloid deposits, several neurodegenerative diseases, including but not limited to Alzheimer's disease, Parkinson's disease, and prion diseases, have the motif insoluble deposits of protein, known as plaques, aggregates, or fibrils, that are held to be key to the cause of the particular malady. A pharmaceutical composition for the inhibition or elimination of said insoluble deposits of proteins at the time of the invention was seen as desirable by which said malady could be treated [Sipe (1992) & US 5780587]. Therefore it would have been obvious to one skilled in the art at the time of the invention that alpha-synuclein and Aβ are both species of the amyloid component genus.

14. The Examiner notes that Applicant asserts to have cancelled claims 1-10 of Application No. 09/979952 but current USPTO records show said claims as pending. The Examiner further notes that Applicant is correct, a timely filed Terminal Disclaimer may obviate a non-statutory double patenting rejection. Such a Terminal Disclaimer may be filed at a time where allowable subject matter has been identified.

15. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

16. Claims **1-8** and **10** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth at pp. 6-10 ¶13-24 of the previous Office Action (25 July 2003).

17. Applicant traverses this rejection on the following grounds: **(a)** Sigurdsson *et al.* (2002) and Sigurdsson *et al.* (2003) support the claims, **(b)** one would expect similar symptomatic effects and results from prion administration and Aβ in view of the similarity in pathology and analogues results in mouse models described by Sigurdsson *et al.* (2002) and Sigurdsson *et al.* (2003) **(c)** the data in the Specification and the Declaration by Dr. Martin Koller support use the claims to a treatment for prion disorders, **(d)** a pharmacological activity is itself "obviously beneficial to the public" (*Nelson v. Bowler*, 206 USPQ 881, 883 (CCPA 1980)), **(e)** the specification discloses a general strategy and principles for a pharmaceutical composition comprising PrP or other amyloid components and an adjuvant, **(f)** the specification teaches that the administration of particular $A\beta_{42}$ (AN1792) fragments with an immunogenic adjuvant reduces β-amyloid levels within the brains of transgenic PDAPP mice, **(g)** the morphology and properties of all amyloid fibrils are remarkably similar, **(h)** the application discloses a general strategy in which pharmaceutical compositions comprising an agent and adjuvant generate an antibody response against an amyloid component and thus remove the amyloid component or reduce its further accumulation in amyloid depositions in a subject, **(i)** it is premature to drawn any firm conclusions from the results of Wisniewski *et al.* (2002) and Tal *et al.* (2003) unless

these results can be confirmed or further explained by subsequent work, **(j)** the use of an adjuvant favors a desired beneficial response to administration of a prion protein, and **(k)**.

18. Applicant's arguments have been taken into consideration and are not found persuasive for the following reasons.

19. On "**(a)**", MPEP §2164.05(a) Applicant may not use post-filing references to support enablement of the invention. Both Sigurdsson *et al.* (2002) (**IDS#384**) and Sigurdsson *et al.* (2003) (**IDS#396**) were published after the instant filing data and therefore cannot be used to supplement or support Applicant's claim that the invention as enabled at the time of filing. Any additional evidence may only be entered into the record by Applicant by means of a Declaration under 37 C.F.R. §1.132.

20. On "**(b)**", prion disorders and Alzheimer's disease are striking different disorders which do not overlap in symptoms, causative agents, mouse models, or therapies. Therefore no reasonable extrapolation can be made form a prion disorder to Alzheimer's disease. The references and data in the instant Specification concerning Aβ are compelling although it was done in an art-accepted model for Alzheimer's disease. This is not the case with PrP. No nexus between PrP immunizations, whether passive or active, has been established with a prion disorder. Further, Brown *et al.* (June 1997) "PrP and β-Amyloid Fragments Activate Different Neurotoxic Mechanisms in Cultured Mouse Cells." European Journal of Neuroscience **9**(6): 1162-1169 teaches that PrP and Aβ, although similar, exhibit fundamentally different neurotoxic effects on neurons (Table 2). Thus one cannot reliably use data from Aβ to predict the activity, mechanisms, or effects of PrP that may be used in active immunization.

21. On "**(c)**" concerning *In re Brana*, no requirements for human testing have been set forth herein or the previous Office Action (25 July 2003). In addition, the Court ruling in *In re Brana* more accurately addresses the question of the threshold of evidence set by the preamble of the claims. In *In re Brana* claims directed to a "cure" were insufficiently supported by animal data. However, the Examiner in that case erred in that the animal model data was sufficient to support "treatment". The only relevance between *In re Brana* and the instant application is that Applicant has claimed a treatment of prion disorders but has included no data whatsoever to support these claims. All the data in the instant Specification is drawn to Alzheimer's disease.

22. On "**(d)**" concerning *Nelson v. Bowler*, 206 USPQ 881, 883 (CCPA 1980), the fact pattern of that case is not analogous to the instant application. No question of pharmacological activity has been raised. The Examiner has rejected the claims for failing to meet the enablement requirement as no activity for any prion related agent has been disclosed.

23. On "**(e)**", the specification as filed does not provide any guidance or examples that would enable a skilled artisan to make or use any pharmaceutical composition for prion disorders in a patient. As discussed in the previous Office Action (25 July 2003), in order to practice the invention using the specification and the state of the art as outlined below, the quantity of experimentation required to practice the invention as claimed would require the *de novo* determination of formulations with known prion proteins, prion disorder signs and symptoms to correlate with activity of said pharmaceutical composition. In the absence of any guidance from the specification, the amount of experimentation would be undue, and one would have been unable to practice the invention over the scope claimed (see also written description rejection of claims 1-8 and 10 included herein).

24. On "**(f)**", administration of $A\beta_{42}$ to Alzheimer's patients is not predictive of how administration of PrP affects patients with prion-related diseases or any given amyloid dependent disorders. There are no examples directed to PrP, diseases caused by PrP, or art-accepted PrP animal models. Additionally, a person skilled in the art would recognize that predicting the efficacy of using a possibly toxic protein based solely on the performance of a different protein is highly problematic [see Weissman & Aguzzi (1997) "Bovine Spongiform encephalopathy and early onset variant Creutzfeldt-Jakob disease." Current Opinion in Neurobiology **7**: 695-700 (**IDS#172**)]. For example, Hsiao (1997) "From prion diseases to Alzheimer's disease." J Neural Transm Suppl. **49**: 135-144 teaches that Alzheimer's disease (AD) and prion diseases differ on the location of their pathogenesis and the protein which lead to their respective pathogenesis (pp. 137-138) (**IDS#122**). The β-amyloid and the prion proteins are different as are the animals models used to study them. Thus it has not been established that AD animal models and data derived from them can translate to predictions on the success of prion proteins. Thus, although the specification prophetically considers and discloses general methodologies of using the claimed method for treatment of prion diseases and/or disorders, such a disclosure would not be considered enabling since the state of prion diseases and/or disorders is highly unpredictable.

25. On "**(g)**", the language of the claims in so far as they read on "prion disorders" encompasses all prion disorders which include Creutzfeldt-Jakob disease (CJD), kuru, fatal familial insomnia, familial thalamic dementia, and Gerstmann-Sträussler-Scheinker disease (GSS). Goldfarb and Brown (1995) "The Transmissible Spongiform Encephalopathies." Annu. Rev. Med. **46**: 57-65 (**IDS#388**) teaches that prion disease also known as transmissible spongiform encephalopathies (TSEs) encompasses kuru, Creutzfeldt-Jakob disease (CJD),

Gerstmann-Sträussler-Scheinker disease (GSS), and fatal familial insomnia (Abstract). All of these diseases share a common element of a prion protein however the diseases are caused by different mutations and various isoforms may or may not be infectious (Table 1 and Table 2). In addition, Kovács *et al.* (2002) "Mutations of the Prion Protein Gene." J. Neurol. **249**: 1567-1582 teaches that different mutations of the prion protein gene are responsible for different diseases with differing ages of onset and severity (Tables 1 and 2; Figures 4 and 5). Thus the skilled artisan is confronted with an undue burden of experimentation and unpredictability on how each individual isoform and/or mutation will affect the immune system of a patient [see also Elan Press Releases (1 March 2001 and 18 January 2002)].

26. Furthermore, regarding derivatives and fragments of PrP (i.e. "components") encompassed by the claims, the skilled artisan readily recognizes that protein chemistry is an unpredictable area of biotechnology. Proteins with deletion, insertion or substitution/replacement of single amino acid residues may lead to both structural and functional changes in biological activity and immunological recognition, see in particular Skolnick & Fetrow (2000) "From genes to protein structure and function: novel applications of computational approaches in the genomic era." Trends in Biotech. **18**(1): 34-39 (**IDS#337**). For example, Jobling & Holmes (1991) "Analysis of structure and function of the B Subunit of cholera toxin by the use of site-directed mutagenesis." Molecular Microbiology **5**(7): 1755-67 (**IDS#334**) teaches a panel of single amino acid substitutions by oligonucleotide directed mutagenesis which produce proteins that differ in native conformation, immunological recognition, binding and toxicity. The skilled artisan further recognizes that immunological responses may depend upon the structural characteristics (conformation) of the particular protein

(amino acid sequence) targeted. Thus, both biological function and immunological recognition are unpredictable properties which must be experimentally determined. Further it is noted, that for particularly small peptides, conjugation appears to be required for promoting an effective immune response.

27. On "**(h)**" the disclosure of a "general strategy", the PDAPP mouse is a representative mouse model of Alzheimer's disease but not prion disorders {see Aguzzi & Weissman (23 October 1997) "Prion research: the next frontiers." Nature **398**: 795-798 **(IDS#391)**}. Furthermore, the skilled artisan must take the ancillary effects of the introduction of an immune response in a mammalian nervous system into consideration. The specification must establish that the antigens injection into the subjects produce a specific immune response and do not act as pyrogens (leading to cranial swelling for example). Due to the large quantity of experimentation necessary to evaluate all the effects of the difficulty of predicating an immune response in the nervous system, the lack of direction/guidance presented in the specification about collateral damage due to a vigorous immune response in an immunological privileged area (such as the nervous system), the absence of working examples directed to successful antigen presentation of a neurological protein, the complex nature of the invention, the unpredictability of the effects of antigens on the mammalian nervous system, and the breadth of the claims which fail to recite limitations for what constitutes a successful, controlled immune response in the mammalian brain, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

28. On "**(i)**", both references were cited to demonstrate the remaining unpredictability of the art. None of the obstacles identified by neither the prior art nor the existing art have been adequately addressed by applicant.

29. On "**(j)**", Applicant's statement is made in the absence of evidence and thus cannot be fully supported. The prior art, Harmeyer *et al.* (April 1998) "Synthetic peptide vaccines yield monoclonal antibodies to cellular and pathological prion proteins of ruminants." Journal of General Virology **79**(4): 937-945 teaches that immunization of mice with 16 synthetic peptides derived from PrP with an adjuvant yielded monoclonal antibodies which vary in their species specificity, Ig class, and strength of binding to PrP (Table 2 & 3; Figure 3). Thus the skilled artisan is left with additional experimentation for the skilled artisan to first make PrP peptides, administer them, and then characterize the immunological response (production of antibodies) to determine which PrP peptides produce the desired effect, with or without an adjuvant.

30. On "**(k)**", Goldsby *et al.* (2002) Kuby Immunology Chapter 18 "Vaccines" (pp. 449-465) teaches that active immunization is not predictable as peptides are not generally immunogenic. Thus the skilled artisan is confronted with undue burden of experimentation to determine which PrP peptides are useful for practicing the invention as claimed. Also Diomede *et al.* (1996) "Activation effects of a prion protein fragment [PrP-(106-126)] on human leucocytes." Biochem. J. **320**: 563-570 teaches that a fragment of PrP, residues 106-126 is toxic to neurons and astrocytes *in vitro* but stimulates neutrophils, monocytes, and lymphocytes, also *in vitro* (Figure 6). Thus PrP may be toxic to some cells but not to others. Diomede *et al.* also points out that immune cells may be able to survive the toxic effects of PrP because they are constantly dividing thus allowing for their numbers to be replenished following exposure to PrP (pp. 569). Thus the

skilled artisan is confronted with an unpredictability of the effects of prion precursor protein and its fragments on cells.

31. Thus the rejection of claims 1-8 and 10 under 35 U.S.C. §112 ¶1 is hereby maintained.

32. Claims **1-8** and **10** are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

33. The claims require "*agent effective to induce an immune response against an amyloid component*". The claims do not require that the agent to possess any particular conserved structure, or other distinguishing feature, such as a specific biological activity. Furthermore the art recognizes that "agent" can pertain to chemical entities, pharmaceutical compositions, proteins, peptides, non-peptide compounds, animal tissue extracts, nucleic acids, antisense molecules, peptidomimetic, transformed cells, radiation, antibodies, antibody fragments, cyclic peptides, agonists, antagonists, inhibitors, enhancers, vegetable extracts, cell extracts, synthetic agents, biologically derived substances as well as proteinaceous substances, known, and unknown compounds.

34. In addition, Applicant has admitted on the record (Response filed 29 December 2003) that no known agent was in fact in the possession of the inventors at the time of filing as Applicant has clearly stated "*the specification discloses a general strategy and principles*" for a pharmaceutical composition comprising PrP or other amyloid components and an adjuvant (pp.

15 of Response filed 29 December 2003). Thus, the claims are drawn to a genus of agents that is defined only by a desired activity.

35. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, and any combination thereof. In this case, the only factor present in the claim that is disclosed is a recitation of a desired activity. The specification does not identify any particular portion of the structure that must be conserved, nor does it provide a disclosure of structure/function correlation. The distinguishing characteristics of the claimed genus are not described. Accordingly, the specification does not provide adequate written description of the claimed genus.

36. To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; see also *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 [41 USPQ2d 1961] (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); *In re Gosteli*, 872 F.2d 1008, 1012 [10 USPQ2d 1614] (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed"). Thus, an applicant complies with the written-description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious,"

and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572.

37. See *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424 (DC WNY 2003) and *University of Rochester v. G.D. Searle & Co. et al.* CAFC [(03-1304) 13 February 2004]. In *University of Rochester v. G.D. Searle & Co.* a patent directed to method for inhibiting prostaglandin synthesis in human host using an unspecified compound, in order to relieve pain without side effect of stomach irritation, did not satisfy written description requirement of 35 U.S.C. §112, since the patent described the compound's desired function of reducing activity of the enzyme PGHS-2 without adversely affecting PGHS-1 enzyme activity, but did not identify said compound, since invention consists of performing "assays" to screen compounds in order to discover those with desired effect. The patent did not name even one compound that assays would identify as suitable for practice of invention, or provide information such that one skilled in art could identify suitable compound. And since specification did not indicate that compounds are available in public depository, the claimed treatment method cannot be practiced without compound. Thus the inventors cannot be said to have "possessed" claimed invention without knowing of a compound or method certain to produce compound. Thus said patent constituted an invitation to experiment to first identify, then characterize, and then use as a therapeutic a class of compound defined only by their desired properties.

38. *University of Rochester v. G.D. Searle & Co.*, 68 USPQ2d 1424 (DC WNY 2003) is of particular relevance as Applicant has admitted on the record that "*the application discloses a general strategy in which pharmaceutical compositions comprising an agent and adjuvant generate an antibody response against an amyloid component and thus remove the amyloid*

component or reduce its further accumulation in amyloid depositions in a subject." (Response filed 29 December 2003 pp. 17). No actual agent was identified nor any specific and concrete guidance given to its nature, structure, origin, physical parameters, chemical composition, mechanism, activity, or identity. The specification has only delineated the desired outcome of a strategy to identify, characterize, and use such an agent.

39. Therefore the full breadth of the claim fails to meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision.

Summary

40. No Claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on **(571) 272-0887**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see **http://pair-direct.uspto.gov**. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN
March 25, 2004

GARY KUNZ
SUPERVISORY PATENT EXAMINER
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